

# Arisure<sup>®</sup> Closed Vial Adapter Mechanically Closed

## Introduction

The Arisure Closed Vial Adapter is designed and constructed to be mechanically closed, prohibiting the escape of hazardous drug and vapor concentration into the environment. This paper presents an overview of the methods and testing used to demonstrate the mechanically closed functionality of the Arisure Closed Vial Adapter.

## Procedure

20mm Closed Vial Adapters were attached to 50mL vials. A 60mL syringe was filled with air and attached to the Closed Vial Adapters. The device was then submerged underwater and 30mL of air was injected into the vial. The submerged device was observed for 15 seconds. A failure was recorded if bubbles originated from the vapor bell, intake check valve, or vial/device interface. A 7-day mechanically closed test was also conducted on sterilized 20mm Closed Vial Adapters that were attached to 50mL vials and allowed to sit for 7 days. A 60mL syringe was filled with air and attached to the Closed Vial Adapters. The device was then submerged underwater and 30mL of air was injected into the vial. The submerged device was observed for 15 seconds. A failure was recorded if bubbles originated from the vapor bell, intake check valve, or vial/device interface.

## Results

Mechanically Closed Test (T=0)	
Configuration	Device does not leak at 30cc injected air
13mm CVA	35/35 Pass
20mm CVA	35/35 Pass
28mm CVA	35/35 Pass

Mechanically Closed Test (T=7 Days)	
Configuration	Device does not leak at 30cc injected air
20mm CVA	30/30 Pass

## Conclusions

The Arisure Closed Vial Adapter passed all testing at 30mL injected air. The results demonstrate that the Arisure Closed Vial Adapter is mechanically closed.

Data on file at Yukon Medical. Arisure Closed Vial Adapter Mechanically Closed Whitepaper TSD 009.01.

# Arisure<sup>®</sup> Closed Vial Adapter Non-Coring

## Introduction

The Arisure Closed Vial Adapter 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<sup>1</sup>. This paper presents an overview of the methods and testing used to demonstrate the non-coring functionality of the Arisure Closed Vial Adapter.

## 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, which have the same vial spike material and geometry as the Arisure Closed Vial Adapter. The tested devices were accelerated heat aged to one year equivalent and three years equivalent. The T=0 and T=6mo 13mm VVADs were tested with three types of stoppers (Lyo, Flurotec, and Siliconized). All other devices were tested with Flurotec stoppers.

## 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. Since the Arisure Closed Vial Adapter and the VVADs have the same spike material and geometry, the results demonstrate that the Arisure Closed Vial Adapter does 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. Arisure Closed Vial Adapter Non-Coring Whitepaper TSD 011.01.