

# SmartSite® VialShield maintenance of drug vial sterility

## Introduction

The SmartSite® VialShield has been designed to maintain the sterility of attached drug vials. The maintenance of the sterility in compounded sterile preparations (CSPs) is an essential requirement for closed vial adapters in order to permit the extension of the beyond-use date of the CSP. The design of the SmartSite VialShield device only permits entry of air into the attached vial that has passed through a 0.2 micron filter. This contrasts with some other closed vial adapter designs that require the drug vial and adapter to be primed with a volume of unfiltered air when accessing prepared drugs. The SmartSite VialShield's 100% filtration of all introduced air blocks the entry of contaminating microorganisms into the CSP. This paper describes the investigation that verified the ability of the SmartSite VialShield to maintain the sterility of an attached vial for seven days.

## Procedures

61 SmartSite VialShield devices were radiation sterilized and provided to the University of North Carolina Eschelman School of Pharmacy for evaluation in a USP <797> compliant compounding environment.

On day 0, the 61 test devices were attached to 25 mL vials, containing sterile, Tryptic Soy Broth (TSB). Each SmartSite VialShield valve was then disinfected with 70% isopropanol in accordance with the directions for use (DFU). 5 mL of the TSB was withdrawn from the SmartSite VialShield using a Texium® closed male Luer affixed to a 10 mL syringe. Each withdrawn 5 mL of TSB was then injected into a uniquely numbered IV bag containing 50 mL of sterile TSB. SmartSite VialShield devices were then stored and attached to the TSB vials until the next day's testing.

Subsequent days repeated the day 0 procedures: disinfecting the valves, withdrawing 5 mL, and injecting it into new, sterile IV bags containing TSB—with the SmartSite VialShield devices attached to the original, day 0, vials.

Samples were withdrawn on days 0, 1, 2, 3, and 7. A total of 305 IV bags were collected over this seven

day period, with each bag containing the unique TSB vial withdrawal of a given SmartSite VialShield on a given day. Each collected IV bag was incubated at 35 °C, and inspected daily for growth of microorganisms for a period of 14 days.

## Negative controls

Six negative controls were tested each day for a total of 30 negative controls. For each negative control, a Texium closed male luer affixed to a 10 mL syringe was used to access an IV bag containing 50 mL of sterile TSB. Each bag was then incubated at 35 °C, and inspected daily for a growth of microorganisms for a period of 14 days.

## Positive controls

Five positive controls were tested. Each positive control injected 5 mL of a diluted bacteria suspension (~0.5 CFU/mL) into a IV bag containing 50 mL of TSB. Each bag was then incubated at 35 °C, and inspected daily for a growth of microorganisms. Five different bacteria were used, one for each of the five controls: Escherichia coli, Enterococcus faecalis, Klebsiella pneumoniae, Pseudomonas aeruginosa and Staphylococcus aureus.

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Results					
	Samples with growth day 0	Samples with growth day 1	Samples with growth day 2	Samples with growth day 3	Samples with growth day 7
Test devices	0/61	0/61	0/61	0/61	0/61
Negative controls	0/6	0/6	0/6	0/6	0/6

All five of the positive controls exhibited visible growth within 24 hours.

**Conclusions**

Of the 305 test samples taken over a seven-day period, zero produced evidence of contamination. This demonstrates that the SmartSite VialShield device, when used and stored in a USP <797> compounding environment, is capable of maintaining the sterility of an attached drug vial.

Positive controls demonstrate that contamination is detectable when low concentrations of drug-contaminating organisms are introduced.

Had contamination occurred, negative controls would have helped to identify whether the contamination occurred because of vial contamination, or because of storage and handling of the test samples independent of the VialShield devices.

Data on file at Yukon

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