SmartSite® needle-free valve microbial contamination study

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Introduction

This purpose of this study is to demonstrate that microorganisms entrained in the area outside of the SmartSite® needle-free valve piston and between the clear housing do not enter the fluid path after multiple valve activations over an extended period of time. The study simultaneously tested the effectiveness of the lower seal (between the blue piston and the rigid clear housing) and the seal of the male luer tip to the access surface of the piston.

Method

Staphylococcus epidermidis (S. epidermidis) as chosen as the challenge organism due to its known presence in the clinical environment and ease of identification. The challenge organism was incubated, harvested and adjusted to approximately 1.0 x 10^5 CFU/mL in 0.1% peptone water (PEPW).

The SmartSite® valves used in the procedures were prepared for testing by creating an opening through the clear rigid housing in the area of the piston. A small 30 gauge needle and syringe were then used to inoculate the valve through this opening to achieve approximately 300-1,000 CFUs of ***S. epidermidis***. The opening in the valve housing was then sealed, and the exterior surfaces of the valves disinfected using 70% isopropyl alcohol (IPA).

Single access challenge

The top access surfaces of 20 SmartSite® valves (inoculated test articles) were cleaned using 70% isopropyl alcohol. The luer slip connector of a sterile syringe pre-filled with saline was connected to each SmartSite® valve to ensure patency using a semi-automated test fixture. The valves were then placed in a clean environment (HEPA hood) for 72 hours after which each valve was flushed with saline. The flushed solution was collected, assayed, incubated and then examined.

Single access positive controls were made by inserting a 22 gauge needle through the access surface of five SmartSite® valve pistons that had been prepared and inoculated previously in the identical manner as the test articles. Saline was injected and withdrawn through the needle and then removed. The syringe contents were collected, incubated and then examined for the presence of ***S. epidermidis***.

Single access negative controls consisted of five sterile SmartSite® valves that had not been exposed to the challenge organism.

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Multiple access challenge

The top access surfaces of 20 SmartSite® valves (inoculated test articles) were cleaned using 70% isopropyl alcohol. Each valve was activated (accessed) and deactivated (de-accessed) with a male luer connector to full engagement 35 times each day for a total of 105 activations over 72 hours using a semi-automated test fixture. After the activation cycles had been completed, the valves were flushed with a minimum of 10 mL of saline which was collected, assayed, incubated and examined. The procedures for activation, deactivation and sample assay were performed every 72 hours until evidence of mechanical or microbial failure was indicated.

Note: Data collected after 72 hours is for information purposes only.

Multiple access positive controls were made by inserting a 22 gauge needle through the access surface of 25 SmartSite® valve pistons prepared and inoculated previously. Saline was injected and withdrawn through the needle and then removed. The syringe contents were collected, incubated and then examined for the presence of ***S. epidermidis***. Testing was to continue every 72 hours thereafter until the positive controls failed.

Multiple access negative controls consisted of five sterile SmartSite® valves that had not been exposed to the challenge organism.

Organism titer per device (CFU)	Exposure time	Number of samples challenged	Number of samples demonstrating growth
~2.6 x 10^5	72 hours	20	0
Positive controls		5	5
Negative controls		5	0

Table 1: Single access results

Organism titer per device (CFU)	Exposure time	Number of samples challenged	Number of samples demonstrating growth	Positive controls demonstrating growth
2.7 x 10^{4*}	72 hours	20	0	Yes
~2.5 x 10^{3*}	144 hours	20	0	Yes
3.2 x 10^{2*}	216 hours	20	0	No
2.3 x 10^{2*}	288 hours	20	0	No
Negative controls		5 per essay	0	N/A

Table 2: Multiple access results

* These values were taken from the prepared test culture that was maintained in the refrigerator and may not demonstrate the actual number of surviving organisms in the challenged device.

Acceptance criteria included that all positive controls must be positive for the challenge organism for the time point to be valid and all negative controls must be negative for the challenge organism for that sample test to be valid.

Results

All test samples demonstrated no growth of the challenge organism after 72 hours (Tables 1 and 2). The multiple access challenge was successful in demonstrating no growth of the test organism for 2 consecutive 72 hour periods, which equated to 144 hours or 210 activations (accesses) and deactivations (de-accesses) prior to failure of the positive controls to demonstrate challenge organism growth.

Conclusion

Microorganisms entrained in the area outside of the SmartSite® valve piston do not enter the fluid path after multiple valve activations over an extended period of time. The lower seal between the piston (blue) and the rigid housing (clear) and the seal of the male luer tip to the access surface of the pistons of the SmartSite® valve are effective in maintaining a closed system. Therefore, the integrity of both seals is maintained after multiple valve activations/deactivations as specified by the *Directions for Use*.

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