STUDY SUMMARY

Microbial Barrier Performance Study of SwabCap™ on Needlefree Connectors

Report of a study commissioned by ICU Medical, Inc. and conducted by Ethox International

PURPOSE

The purpose of this study was to evaluate the microbial barrier performance of SwabCaps on needlefree connectors and their ability to maintain a disinfected surface on connectors seven days after application, if not removed.

METHODS

A protocol was developed and executed by Ethox International™ comparing the potential for aerosol microbial contamination of needlefree connectors covered with a SwabCap and needlefree connectors that were not covered with a SwabCap across 15 different needlefree connector types. Twelve needlefree connectors from each of the 15 needlefree connector types were used for positive controls (uncovered needlefree connectors, exposed, and recovered).

One SwabCap was placed on each needlefree connector. The caps were then over-torqued twice to provide the opportunity for the worst case fit of the SwabCap onto each needlefree connector and further limit the barrier properties of the device. Capped needlefree connectors were left at ambient temperature (20-25°C) for 7 days to simulate the effects of a 7-day period of use including any drying out of the disinfectant or relaxing of the cap material which might affect the barrier properties of the device.

AEROSOL PREPARATION

Nine (9) mL of saline test solution (saline TS) was inoculated with an appropriate amount of a Bacillus atrophaeus (Ba) spore suspension to achieve final concentration of approximately $1.0x10^7$ colony forming units (cfu)/mL. Serial dilutions were made and plated with Tryptic Soy Agar (TSA) to determine the actual concentration.

Plates were incubated at 30-35°C for 18-48 hours, then counted using colony counter and counts recorded.

MICROBIAL BARRIER PERFORMANCE PROCEDURE

Capped (test) and uncapped (control) needlefree connectors were suspended in the aerosol chamber so they did not touch each other. Six (6) fallout plates containing TSA and four sterile gauze sponges (4 sq. in.) were placed in the chamber to serve as positive controls. Five (5) mL of inoculated saline TS was pipetted into a DeVilbiss Nebulizer attached to the chamber and a regulated nitrogen tank. The inoculated buffer was aerosolized into the chamber. After aerosolization the fans were allowed to run for 30-35 minutes, and then turned off. The chamber was allowed to remain stationary for a minimum of 30 minutes.

Each sample was removed from the chamber. The exterior of the capped needlefree connectors were decontaminated with UV light for 5 minutes.

Caps from the test samples were removed and each test was recovered by swabbing with a sterile cotton swab pre-wetted with sterile phosphate buffer with 0.1% polysorbate 80. The swab was then transferred to 10 mL of sterile phosphate buffer with 0.1% polysorbate

It was determined the SwabCap disinfecting cap provides an effective microbial barrier to the top surface of all luer access needlefree connectors tested and maintains a disinfected surface on the connectors seven days after application, if not removed.

80, vortexed, and either 0.1 or 1 mL of the buffer was plated to obtain a countable range. Test and control plates were incubated at 30-35°C for 18-48 hours. After incubation, the plates were counted and counts recorded.

The gauze sponges were removed from the aerosol challenge chamber and extracted in 50 mL volumes of phosphate buffer with 0.1% polysorbate 80 for 30-35 minutes. After extraction, 0.1 and 1 mL aliquots were plated in duplicate with TSA, then plates were incubated at 30-35°C for 18-48 hours. After incubation, the plates were averaged and multiplied by 50 or 500 to determine the total number of organisms on the gauze swatch. The value was divided by 4 to determine the average challenge delivered to each package, reported in cfu/in^2.

Fallout plates were removed from the chamber and incubated at 30-35°C for 18-48 hours. Due to high fallout, three, one cm^2 sections of each plate were counted and recorded. The average of those three sections represents the average fallout in cfu/cm^2 of each plate. The fallout on each plate was averaged to represent the average challenge (cfu/cm^2) delivered in the chamber.

TEST RESULTS

The average recovered organism count for the uncapped needlefree connectors ranged from 1.1×10^3 to 9.3×10^2 cfu's. The average recovered organism count for the SwabCap-capped needlefree connectors ranged from 0.0 to 1.2 cfu's. On all needlefree connectors tested, the SwabCap provided at least a 2.77 log difference in the amount of aerosolized organisms allowed to contaminate the top surface and threads of the connector.

CONCLUSION

Based on results of the microbial barrier performance testing above, it was determined that the SwabCap disinfecting cap provides an effective microbial barrier to the top surface of all luer access needlefree connectors tested after seven days, and is an effective way to maintain an antiseptic condition on the surface of the needlefree connector. Per the device's FDA 510(k) clearance, the SwabCap disinfecting cap prevents the transfer of environmental contaminants, including bacterial and airborne contaminants into the system.

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human connections