

Extended Use Microbial Challenge and Disinfection Study of the CLAVE® Connector

Introduction

ICU Medical, Inc. of San Clemente, California has been manufacturing and marketing the CLAVE Connector since 1993. New standards in IV therapy are being directed towards longer use life for connecting devices such as the CLAVE Connector. In order to reduce costs yet maintain quality medical care, products proven to be effective in the hospital as well as alternate site for longer than the recommended usage, will better suit the needs of some health care agencies. In the interest of safety and efficacy, ICU Medical has microbially challenged the CLAVE Connector in this study for a period of six days using multiple activations in order to validate its ability to maintain a physical microbiological barrier. The CLAVE Connector is a swabable system, as well as a physical barrier to bacteria under normal clinical settings.

In this study the CLAVE Connector is microbially challenged to a rigorous use model in order to demonstrate its integrity when subjected to what would be considered a worst case clinical scenario. Samples of the CLAVE were artificially contaminated with *Pseudomonas aeruginosa* in order to determine if it can thereafter be effectively decontaminated with a standard disinfection protocol. *Pseudomonas aeruginosa* in a 8.9×10^3 population was selected as the challenge organism for its aggressive characteristics in a clinical environment. The CLAVE is designed to maintain a physical barrier with repeated exposure to microorganisms. The samples were accessed using twenty four (24) bolus pushes of sterile saline every twenty four (24) hours for a period of six (6) days to demonstrate the worst case clinical model. The multiple activations and the duration of the study were chosen to show the integrity of the product as a "stressed" system.

Protocol

To validate the ability of the CLAVE Connector to prevent microbial contamination, Laboratory Services, Inc. of Monrovia, California was contracted to perform the independent study. Twenty samples of the CLAVE were selected as required by the United States Pharmacopoeia (USP) for sterility testing. The test also included a positive control, negative control, and four population verification samples. The twenty test samples and the controls were challenged against the simulated use model. The test units were assembled onto individual sterile filter funnel units. Each of the twenty samples and the positive control were inoculated with an average of more than 870 colony forming units (CFUs) as confirmed by the population verification samples. To simulate the worst case clinical model, the samples were then disinfected with a 70% sterile alcohol swab and accessed with a 10mL bolus push of sterile saline. The saline wash was passed through the filter into

funnel unit, and the filter membrane was then incubated in SCDB for seven days or 168 hours at 32-35°C. Any microbial contaminants were identified and characterized. The positive control was flushed with 10mL of a nominal 1.0×10^2 /mL volume of challenge suspension. The negative control was processed by eliminating the inoculation procedure.

Results

The study indicated no microbial contamination of the CLAVE Connector for six days or 144 hours. Initial contamination of the CLAVE was verified to be at least 870 CFUs per sample on average. The ability of the CLAVE Connector to maintain its integrity as a "stressed" system when microbially challenged under a worst case clinical simulation is demonstrated in the following table.

Time	Number samples positive for <i>P. aeruginosa</i>	Positive Control	Negative Control
24h	0/20	1/1	0/1
48h	0/20	1/1	0/1
72h	0/20	1/1	0/1
96h	0/20	1/1	0/1
120h	0/20	1/1	0/1
144h	0/20	1/1	0/1

Conclusion

In all cases the CLAVE Connector was able to maintain a physical barrier for 144 hours (six days) while administering 24 repeat activations per day for a total of 144 activations. The study results indicate that the CLAVE Connector when using a standard disinfection protocol did not increase infection rates under a worst case clinical simulation.

Recommendations

- Use aseptic technique and accepted IV practice.
- Swab CLAVE Connector using desired disinfectant in accordance with facility protocol.
- Flush CLAVE Connector after each use in accordance with facility protocol.
- Change the CLAVE Connector according to CDC Guidelines or validated facility protocol.