

Extended use microbial challenge and disinfection study of the Clave[®] connector

An independent study conducted by Laboratory Services, Inc., Monrovia, CA

PURPOSE

The Clave needfree connector is designed to maintain a physical microbiological barrier under repeated exposure to microorganisms. The purpose of this study was to validate that ability in a worst-case clinical scenario under a rigorous use model. The multiple activations and the duration of the study were chosen to test the integrity of the product as a stressed system. *Pseudomonas aeruginosa* was chosen as the challenge organism for its aggressive characteristics.

MATERIALS AND METHODS

Twenty Clave samples, one positive control, and one negative control were attached to individual sterile filter funnel units. The female end of 20 samples and one positive control were inoculated with an average of more than 870 CFUs *P. aeruginosa*. The negative control was not inoculated. Each sample was disinfected with a 70% sterile alcohol swab. To simulate the worst-case scenario, the samples were accessed with a 10 mL bolus push of sterile saline every 24 hours for 144 hours.

The saline wash was passed through the filter into the funnel unit, and the filter membrane was incubated for seven days. The positive control was flushed with 10 mL of a 1.0 X 10²/mL volume of challenge suspension. Four additional samples were used to verify population count of *P. aeruginosa*.

RESULTS

Initial contamination of the Clave with *P. aeruginosa* was verified to be at least 870 CFUs per sample on average. The results showed no microbial contamination of the Clave connector for 144 hours. Results are shown in the table.

Time (h)	Samples Positive for <i>P. aeruginosa</i>	Positive Control	Negative Control
24	0/20	1/1	0/1
48	0/20	1/1	0/1
72	0/20	1/1	0/1
96	0/20	1/1	0/1
120	0/20	1/1	0/1
144	0/20	1/1	0/1

CONCLUSION

Under this worst-case swabbing clinical scenario, the Clave fluid pathway maintained a physical barrier to microbial ingress for the entire study. The Clave connector's physical barrier remained impervious for 144 hours (six days) under repeated activations and normal disinfection. No microbes were found in the connector after disinfecting, swabbing, and flushing. When using a standard disinfection protocol, the Clave does not permit microbial ingress.