STUDY SUMMARY

Experimental microbial challenge and decontamination of Clave® connectors

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PURPOSE

The purpose of this laboratory study was to determine whether the Clave connector, when challenged with Pseudomonas aeruginosa, could maintain a sterile barrier following decontamination with 70% isopropyl alcohol. P. aeruginosa was chosen as the challenge organism because of its motility. The protocol was designed to simulate clinical practice.

MATERIALS AND METHODS

Decontaminations were performed using one 70% isopropyl alcohol prep pad one time. Soybean Casein Digest Broth (SCDB) Growth Media was used for the flushes.

Experiment 1: Decontamination	The silicone septums of 20 Clave connectors were inoculated with P. aeruginosa and decontaminated. The Claves were then flushed and incubated for seven days. Test units were decontaminated and engaged in 20 replicate use simulations per unit and cultured after each activation.
Experiment 2: Microbial challenge	Syringes were attached to the decontaminated Clave connectors. Connectors were activated and test units primed; syringes remained connected to the Claves for 72 hours before flushing. Nineteen additional activations and flushes were performed on the 20 decontaminated Clave connectors to determine any positive culture. Clave connectors were immersed in 1 X 104 culture suspension of P. aeruginosa and decontaminated. Test systems were incubated for 24 hours. Media inside were incubated for an additional seven days and tested.
Experiment 3: Pressure testing	Sterile SCDB-filled syringes were connected to 20 Claves at the male luer end using a luer adapter, and then pressure was exerted to fill the void between the silicone seal and the internal piercing element. The units were incubated for seven days and tested.

RESULTS

Effective decontamination of Clave connectors was achieved in 100% of the devices tested. No P. aeruginosa was isolated from any Clave connector after its internal integrity was challenged for microbial growth. Clave connectors maintained a sterile barrier following prolonged and multiple activations.

Experiment 1: Decontamination	All test units of Clave connectors were culture negative after seven days of incubation. No P. aeruginosa growth was observed.
Experiment 2: Microbial challenge	No positive culture of P. aeruginosa was observed in any of the 20 Clave Connectors after a 72-hour engagement period, followed by 19 additional activations.
Experiment 3: Pressure testing	No P. aeruginosa growth was observed in any of the SCDB cultures taken from the male end of the Clave connectors after seven days of incubation. This demonstrates that there was no ingress of P. aeruginosa into the void area between the silicone seal and the internal piercing unit.

CONCLUSION

These experiments show effective decontamination of the Clave connector compression seal with 70% isopropyl alcohol swabbing. The results demonstrate that the Clave fluid pathway lends itself to being flushed clean. The Clave connector is an effective one-unit, closed-system IV device that resists microbial growth.