STUDY SUMMARY

Evaluation of the Clave® technology and resistance to microbial ingress

Report of a study commissioned by ICU and conducted by Nelson Laboratories

PURPOSE

In 2005, the FDA issued standardized microbial ingress testing guidance for premarket approval of new needlefree connectors. In response, ICU voluntarily commissioned Nelson Laboratories of Salt Lake City to subject the Clave, which received premarket approval in 1993, to the new tests.

MATERIALS AND METHODS

Twenty-four Clave connector samples were studied. Sixteen additional connectors were used as controls (eight positive, eight negative). Each test sample received a total of 15 inoculations, 70% isopropyl alcohol (IPA) swab, and 10 mL saline push. Over a three-day period, each sample was inoculated five times a day with a minimum of 103 of each of the four bacterial strains (see table for list), and then disinfected by aggressive circular-motion swabbing with a 70% isopropanol wipe for three seconds. Each sample was then accessed with a sterile syringe and infused with 10 mL sterile saline that was collected in a filter funnel unit. The entire process was repeated four additional times per day for three days. Samples were also subjected to one four-hour extended activation using a sterile 10 mL syringe, and a final activation flushing SCDB* with 5% bovine serum albumin, capturing it in filter units. Positive controls were not disinfected, and negative controls were not inoculated. Collections from the flushes were incubated for seven days prior to bacterial count.

RESULTS

Microorganism Challenge Colony-Forming Unit (CFU)	Repeat Use Simulations (CFU)	Extended Activation (CFU)	SCDB Control (CFU)	Negative Control (CFU)	Positive Control Log Reduction
Staphylococcus aureus	0	0	0	0	3.2
Staphylococcus epidermidis	0	0	0	0	3.7
Klebsiella peneumoniae	0	0	0	0	2.4
Pseudomonas aeruginosa	0	0	0	0	3.2

None of the Claves were contaminated during repeat-use simulations or extended activations. Negative control samples all had zero CFU counts. More than half the positive control samples, which had no disinfection, showed significantly reduced counts compared to the inoculation counts.

CONCLUSION

In this rigorous challenge using high CFU counts, Clave prevented microbial ingress in all cases. Even in the positive controls, which were not disinfected, bacteria passing through the connectors were reduced in number. These results show that the internal fluid pathway design of the Clave is an effective tool for preventing catheter hub contamination.

*Soybean case in digest broth