STUDY SUMMARY

MicroClave™ Neutral Displacement Connector Microbial Ingress Test

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

Objective

A protocol was developed and executed by Alcami (Alcami Corporation, Durham, North Carolina), a leading contract development and manufacturing organization (CDMO), to evaluate microbial ingress on the MicroClave neutral displacement connector over a seven-day period.

Methods

Devices were subjected to a repeated sequence of multiple disinfections and multiple activations. This was followed by inoculation with a microbe known to cause central line-associated bloodstream infections. Devices were then disinfected, and a flush fluid was collected for assay.

Microbial Selection and Culture Preparation

Staphylococcus aureus was selected for this performance test, as it is considered one of the most common infectious pathogens of concern in the clinical setting.

Test organisms from the American Type Culture Collection (ATCC), a nationally recognized culture organization, were inoculated from stock cultures and incubated at a temperature of 30–35 °C to create the 1–5 x 10^3-colony forming units (CFU) minimum inoculation solution.

Microbial Performance Test

Testing was performed in a controlled environment. The test procedure consisted of the following sequential steps: inoculate the clear septum of each of the twenty test devices with 1–5 X 10^3 CFU of Staphylococcus aureus, followed by one minute of drying in ambient conditions, then the top of the surface of the connector was disinfected using a 70% isopropyl alcohol pad for 3 seconds and allowed to dry. The device was then activated using a syringe with 10 mL of sterile 0.9% saline, the fluid was then collected, filtered, and plated to determine growth at 30–35 °C for 2–3 days. Each of the twenty test devices were activated twenty times per day for seven days, totaling 140 activations per device.

Controls

Two positive controls and two negative controls followed the same test procedure as the devices for each type of test organism. The positive controls demonstrated the viability of the challenge organisms throughout the test period. The positive controls were not disinfected after inoculation with the test organism, and the negative controls were not inoculated.

Positive monitor recovery control titers demonstrated that the minimum challenge level meets the United States FDA 2008 intravascular administration set guidance[1] for microbial ingress.

Acceptance Criteria

Negative controls must be negative for the challenge organisms. Positive controls must be representative of the test setup. All study acceptance criteria were met.

Results

Analysis of growth on plated fluid samples found that:

› All devices tested negative for growth (0 CFU), meaning there was no microbial contamination of the device fluid path.

› Negative controls were negative for growth and positive controls tested positive for growth.

Activations per test organism:

› Final total activations/test device: (20 activations) x (7 days) = 140

Staphlococcus Aureus			
	Test Devices 1-20	Positive Controls	Negative Controls
Day 1	0 CFU	+/+	0 CFU
Day 2	0 CFU	+/+	0 CFU
Day 3	0 CFU	+/+	0 CFU
Day 4	0 CFU	+/+	0 CFU
Day 5	0 CFU	+/+	0 CFU
Day 6	0 CFU	+/+	0 CFU
Day 7	0 CFU	+/+	0 CFU

Conclusions

MicroClave neutral displacement connector passed the microbial ingress test, and no contamination was found after repeated use, inoculation, and disinfection with 70% isopropyl alcohol. Therefore, the MicroClave neutral displacement connector is suitable for use for 7 days on the appropriate vascular access or infusion device.

References
1. Guidance for Industry and FDA Staff-Intravascular Administration Sets Premarket Notification Submissions [510(k)]. Document issued on July 11, 2008.