STUDY SUMMARY

Microbial Challenge and Disinfection Study for the Tego® Needlefree Hemodialysis Connector

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PURPOSE

The purpose of this microbial challenge and disinfection study was to evaluate the ability of the Tego needlefree hemodialysis connector, by ICU Medical, Inc., to be effectively disinfected and resist bacterial contamination during a simulated use model.

MATERIALS AND METHODS

The experiment utilized artificial contamination of twenty Tego connectors with Staphylococcus aureus organism suspension (10^3/0.01 mL). Each valve surface was inoculated once a day for a period of seven days. After being air dried at room temperature, the inoculated valve was disinfected (swabbed) at its injection site with a sterile 70 percent Isopropyl Alcohol swab in a circular motion with pressure for three seconds. Four engagements proceeded every day for a total of seven days and 28 total engagements to serve as the simulated use model.

On each engagement, 10 mL of 0.9 percent sterile saline solution was injected through each Tego connector after disinfection swabbing. The solution was collected into a sterile filter funnel unit, and the solution was tested for the presence of the challenge microorganism by membrane filtration method.

RESULTS

The twenty test units of Tego connectors and negative controls showed no organism growth over the seven-day study period. The positive controls showed organism growth, and the count verification of colony forming units (CFUs) showed an average recovery of 12,543 CFUs per sample. After thorough evaluation of test results, the test articles showed the efficacy of microbial resistance. The test results met the acceptance criteria and the decontamination procedures are recommended for future use.

RESULTS TABLE

Sample	Number of Test Units Positive for S. aureus	Positive Control	Negative Control
Day 1	0/20	0/3*	0/2
Day 2	0/20	+/3	0/2
Day 3	0/20	+/3	0/2
Day 4	0/20	+/3	0/2
Day 5	0/20	+/3	0/2
Day 6	0/20	+/3	0/2
Day 7	0/20	+/3	0/2

*No CFU count on the positive control was recovered on day one. This was due to an error in recovery process. This error was corrected for future days and did not adversely affect the study results as all samples maintained a negative recovery for the duration of the study.

SUMMARY

The Tego needlefree hemodialysis connector demonstrated an effective microbiological barrier to bacteria for a seven-day period. The study also demonstrated that the Tego connector can effectively be disinfected using a standard swabbing procedure.