

Extended Use Microbial Challenge and Disinfection Study of the CLC2000®

Introduction

New standards in IV therapy are being directed towards longer use life for intravenous devices such as the CLC2000. To reduce costs yet maintain quality medical care, products proven to be effective in the hospital as well as alternate sites, for longer than the standard usage will better suit the needs of some health care agencies. In this study, ICU Medical has microbially challenged the CLC2000 for a period of seven days using multiple activations to validate its ability to maintain a physical microbiological barrier. The CLC2000 is claimed to be a swabable system, as well as capable of maintaining a physical barrier to bacteria under normal clinical conditions.

In this study the CLC2000 was microbially challenged to a rigorous use model in order to demonstrate its physical barrier properties. Samples of the CLC2000 were artificially contaminated with *Staphylococcus epidermidis* in order to determine if the device can thereafter be effectively decontaminated with a standard hospital disinfection protocol. *Staph. epidermidis*, in a 5.0×10^5 /mL population, was selected as the challenge organism for its known presence in the clinical environment. The samples were accessed using eight bolus pushes of sterile saline every twenty-four hours, for a period of seven days, to demonstrate the worst case clinical model. The multiple activations and the duration of the study were chosen to show the integrity of the product as a "stressed" system.

Protocol

To validate the ability of the CLC2000 to prevent microbial contamination, Laboratory Services, Inc. of Monrovia, California was contracted to perform the independent study. Twenty samples of the CLC2000 were selected as required by the United States Pharmacopoeia (USP) for sterility testing. The test also included a positive control, negative control, and four population verification samples. The twenty test samples and the controls were challenged against the simulated use model. The test units were assembled onto individual, sterile filter funnel units. Each of the twenty samples and the positive control were inoculated with an average of more than 333 colony forming units (CFUs), as confirmed by the population verification samples. The samples were then disinfected with a 70% sterile alcohol swab and accessed with a 10mL

bolus push of sterile saline. The saline wash was passed into the funnel unit and through the filter. The filter membrane was then incubated in SCDA for five days at 32-35°C. Any microbial contaminants were identified and characterized. The positive control was processed by eliminating the swabbing procedure, and the negative control was processed by eliminating the inoculation procedure.

Results

The study indicated no microbial contamination of the CLC2000 for seven days (168 hours). Initial contamination of the CLC2000 was verified to average 1750 CFUs per sample. The ability of the CLC2000 to maintain its integrity as a "stressed" system when microbially challenged under a worst case clinical simulation is demonstrated in the following table.

Time	Number samples positive for <i>Staph. epi</i>	Positive Control	Negative Control
24h	0/20	1/1	0/1
48h	0/20	1/1	0/1
72h	0/20	1/1	0/1
96h	0/20	1/1	0/1
120h	0/20	1/1	0/1
144h	0/20	1/1	0/1
168h	0/20	1/1	0/1

Conclusion

In all cases, the CLC2000 maintained a physical barrier for seven days, while administering eight repeat activations per day. The study results indicate that the CLC2000 when using a standard disinfection protocol, did not result in increased infection rates under a worst case clinical simulation.

Recommendations

- Use aseptic technique and accepted IV practice.
- Swab CLC2000 using desired disinfectant in accordance with validated facility protocol.
- Flush CLC2000 after each use with normal saline or in accordance with facility protocol.
- Change the CLC2000 per CDC Guidelines or per validated facility protocol.

The CLC2000[®] Performance with High Risk Infusates

Introduction:

Some intravenous medications known as high risk infusates, and also referred to as anti-neoplastics, may come in contact with plastic devices or components through intravenous therapy. Such infusates are known to cause damage to plastic devices and may result in an interruption in IV therapy. The CLC2000 by **ICU Medical, Inc.**, is designed to be compatible with most clinical applications as well as those requiring the administration of anti-neoplastics. The following study was conducted to demonstrate the functional integrity of the CLC2000 when exposed to such infusates. The plastic components of CLC2000 are manufactured with polycarbonate, polyester and silicone. The following medications were used to conduct the study; Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.

Procedure:

Sixty samples of the CLC2000 were assembled together to complete one test setup. The test infusate was prepared per the manufacturer's instructions and available in a 5cc luer lock syringe. Water was available in a 5cc syringe to be used as the study control. The syringe containing the test infusate was attached to the proximal end, or injection site of the of the CLC2000 test unit, by fully activating the CLC2000 and securing the luer lock connection. The contents of the syringe were infused through the entire test setup, until an excess of the drug was captured in a second syringe at the distal end, or male luer of the CLC2000. The test setup was a closed system and was monitored for leakage at all of the connection points.

At one hour intervals the samples were tested for patency by pushing at the proximal syringe, and then reversing the action by pushing at the distal syringe. This action was repeated twenty-four times per day, for seventy-two hours, or three days. At all times, each CLC2000 test unit was exposed to the infusate. Following the three days of exposure, the infusate was disposed of per the manufacturer's instructions and the samples were generously flushed to remove any drug residue.

The samples then underwent functional and visual inspection according to the CLC2000 performance specifications. Flow testing was used to identify any degradation of the internal polycarbonate poppet. Backpressure testing to 60 psig was used to identify any degradation of the silicone seal and polyester housing. All samples were visually inspected for degradation. The results of the study are reported in the following table.

Results:

Test Infusate	Flow Rate: number of failures per 60 samples	Backpressure: number of failures per 60 samples	Overall Failure Rate for Test Infusate
Taxol (2mg/mL):	0/60	0/60	0%
Cisplatin (2mg/mL):	0/60	0/60	0%
Adriamycin (3mg/mL):	0/60	0/60	0%
Oncovin (1mg/mL):	0/60	0/60	0%
Lasix (100mg/mL):	0/60	0/60	0%
Control Water:	0/60	0/60	0%

Conclusions:

The CLC2000 met its functional specifications following exposure to the test infusate. According to this study the CLC2000 suffered no functional or visual degradation with Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.